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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,474	10/17/2001	Wilhelmus Theodorus Antonius Maria De Laat	246152012710	8056
25225	7590	10/19/2005		
MORRISON & FOERSTER LLP 3811 VALLEY CENTRE DRIVE SUITE 500 SAN DIEGO, CA 92130-2332			EXAMINER WINSTON, RANDALL O	
			ART UNIT	PAPER NUMBER
			1655	

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/982,474

Applicant(s)

DE LAAT ET AL.

Examiner

Randall Winston

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_\_ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on 07/26/2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 38-68 is/are pending in the application.
- 4a) Of the above claim(s) 38-51 and 64 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 52-63 and 65-68 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Acknowledgement is made of the receipt and entry of the amendment filed on July 26 2005.

The rejection made under 35 U.S.C. 112, second paragraph have been overcome by Applicant's amendment..

Examiner acknowledges that claims 1-37 have been cancelled and claims 38-51 and 64 are withdrawn.

Claims 52-63 and newly added claims 65-68 will be examined on the merits.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 52-63 and 65-68 as amended are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheehan (US 416445 in view of Microbiology, fourth edition, Pelezar, Reid, and Chan pages 853-856).

Applicant argues as amended, the claims exclude alcohols a carbon source. Sheehan, alone or in combination with the Microbiology reference, fails to teach a process comprising fermenting a microbial strain on a volume scale of at least 10 m3, in a fermentation medium containing an amount of complex carbon and/or nitrogen source that is at most about 10% of the total amount of carbon and/or nitrogen. In the absence of ethanol, the carbon sources used in Sheehan are cornsteep liquor (1.8%) and

Art Unit: 1655

glucose hydrate (0.20%). As indicated in the specification, cornsteep liquor is a complex carbon source. Thus, the carbon source in Sheehan, in the absence of ethanol, is primarily composed of corn steep liquor, a complex carbon source.

Applicant's argument is not found persuasive because claims 52-63 as amended and newly added claims 65-68, also are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheehan (US 416445 in view of Microbiology, fourth edition, Pelezar, Reid, and Chan pages 853-856.) Although applicant claims that its fermentation medium has amount of complex carbon and/or nitrogen source that is at most about 10% of the total amount of carbon and/or nitrogen source, applicant claim language uses comprising language. Thus, alcohols are not excluded with the fermentation medium. Sheehan uses 10% ethanol and 1.8% corn steep liquor. Thus, corn steep liquor is intended to be smaller portion of the medium and the amount of a specific ingredient in a fermentation medium is obvious to optimize. Thus, the combination of the two reference does teach the claimed invention because it would have been obvious to one of ordinary skill in the art of creating the claimed invention to modify Sheehan et al.'s teaching and to include the beneficial teachings of Microbiology because the above two combined reference teachings utilizing the same process steps would produce an improved process for the production of Beta-Lactam at an industrialized scale. The adjustment of these and other conventional working conditions (i.e. fed-batch fermentation, the amount of complex and/or nitrogen is at most about 10 %, recovering the Beta-Lactam from the fermentation medium and the substitution of one Penicillin for the another Penicillin (i.e. the substitution of Penicillin V for adipoyl-7-ADCA) utilizing

Art Unit: 1655

the same claimed steps)), is deemed merely a matter of judicial selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

**No claims are allowed.**

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is 571-272-0972. The examiner can normally be reached on 8AM-5PM.

Art Unit: 1655

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Susan D. Coe*  
10-13-05

**SUSAN COE**  
**PRIMARY EXAMINER**